PCT WORLD INTELLECTUAL PROPI International B

INTERNATIONAL APPLICATION PUBLISHED UNDER

WO 9605883A1

(51) International Patent Classification 6 : A61M 39/18 | A1

(11) International Publication Number: **WO 96/05883**

(43) International Publication Date: 29 February 1996 (29.02.96)

(21) International Application Number: PCT/SE95/00795

(22) International Filing Date: 28 June 1995 (28.06.95)

(30) Priority Data:
9402805-7 23 August 1994 (23.08.94) SE

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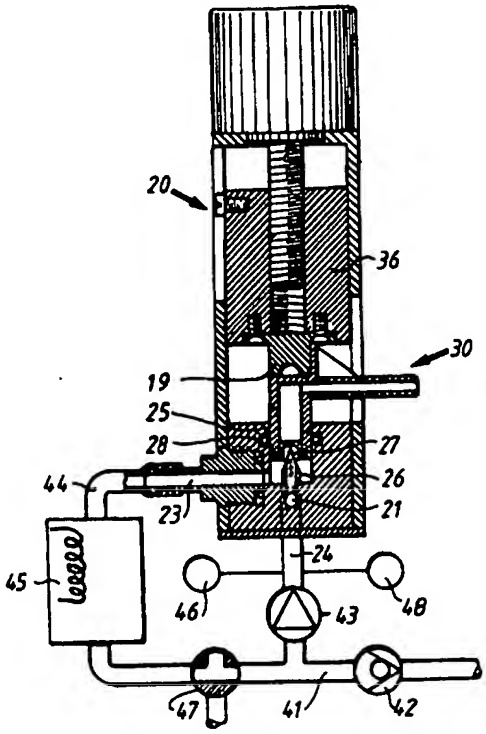
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.

(54) Title: METHOD AND CONNECTION UNIT FOR STERILE TRANSFER OF SOLUTION VIA A CONNECTOR

(57) Abstract

The invention refers to a method for sterile transfer of a solution via a connector (30), and comprises the steps that the inlet (21) of the connector is heat sterilized by flowing a sterilizing solution around the inlet opening of the connector, that a penetrating element (27) is sterilized by flowing a sterilizing solution around the penetrating element, and that the sterilized inlet opening of the connector is penetrated by the sterilized penetrating element and said solution is transferred to the connector via the penetrating element. The invention also refers to a connection unit for sterile transfer of a solution via a connector (30).



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TITLE

Method and connection unit for sterile transfer of solution via a connector.

TECHNICAL FIELD

The invention relates to a method and a connection unit for sterile transfer of solution via a connector.

BACKGROUND OF THE INVENTION

The invention is intended to be used in conjunction with an on-line sterilizing arrangement as described in EP-A1-428 009. This document describes a continuous heat sterilizing arrangement in which a solution is heated during transport in a conduit to a high temperature, for example about 130°C, and maintained at this temperature for a predetermined period for sterilization. Thereafter, the solution is cooled to the temperature at which it is to be used. The sterilization takes place at high pressure which is achieved with a pump and a throttle arrangement.

A heat exchanger is used to provide the heat energy. The sterilization arrangement is used for sterilizing infusion solutions such as Ringer's solution, other medical solutions such as dialysis solutions, purified water to obtain sterilized water or other similar solutions.

The sterilizing arrangement according to EP-A1-428 009 is provided with a shunt conduit which in principle connects the inlet to the outlet so that the solution which is in the system can be circulated in a closed circuit. In this manner, the temperature of the circulating solution can be raised to, for example, 120°C to sterilize the device itself.

The solution which has been sterilized with the above-described sterilizing arrangement can be used directly, for example in dialysis or infusion.

In certain circumstances it is also desirable to transfer the sterilized solution to storage bags for later use, or for delivery to other departments within the hospital. For this purpose, disposable sets of tubes are available which terminate with a bag.

Normally, such bags are filled with medical solution, whereafter the set of tubes is sealed and the disposable article sterilized in its entirety, i.e. with the medical solution within the bag. Such sterilizing can be effected with gamma-sterilization or via autoclaving.

Alternatively, the set of tubes can be provided with medical solution after the set of tubes has been sterilized. In such cases, a sterile connector is normally used which comprises a membrane which is broken when used. Those parts which are connected together are sterile. With such a sterile connector, there is always the risk that bacteria which may reside on the outer side of the membrane are introduced with the connector device and contaminate the interior of the connector.

EP-A1-0 230 864 describes a sterile connection of two containers whereby the connection takes place in a sterilized chamber which is maintained aseptic by means of a chemical disinfectant. Chemical disinfection does not however guarantee sterility and instead the risk for bacteria contamination is still present.

SUMMARY OF THE INVENTION

The object of the present invention is to propose a method and a connection unit which permit sterile connection for transfer of a sterilized solution to a previously sterilized disposable set of tubes in such a manner that bacteria contamination is completely eliminated. The set of tubes can be terminated with a connection bag or may lead to an infusion device or dialysis machine or other medical equipment.

A method and a connection unit which allow the achievement of the above-mentioned object are presented in the subsequent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described in greater detail in the following with reference to the embodiments of the invention shown in the drawings.

Fig. 1 is a schematic view of the sterilizing arrangement according to EP-A1-0 428 009.

Fig. 2 is a view similar to Fig. 1 which shows the connection of a connecting unit according to the invention.

Fig. 3 is a cross sectional view through the connection unit in stand-by position.

Fig. 4 is a cross sectional view through a connector intended to be used in accordance with the invention.

Fig. 5 is a plan view of the connector according to Fig. 4.

Fig. 6 is a view similar to Fig. 3 and shows the connection unit in an open position for introduction of the connector according to Fig. 4.

Fig. 7 is a view similar to Fig. 6 and shows the connection unit with in situ connector in a sterilizing position.

Fig. 8 is a view similar to Fig. 6 and shows the connection unit in a filling position.

Fig. 9 is a cross sectional view similar to Fig. 3 and shows the connection unit in another adaptation.

Fig. 10 is an enlarged cross sectional view of a portion of the connection unit according to an alternative embodiment.

Fig. 11 is a cross sectional view similar to Fig. 3 and shows a further adaptation of the connection unit.

DETAILED DESCRIPTION OF FURTHER EMBODIMENTS

A sterilizing arrangement according to EP-A1-0 428 009 is shown in Fig. 1. A solution which is to be sterilized is introduced via an inlet 5 and flows through a valve 12 to a pump 8. The pump 8 increases the pressure of the solution and pumps the solution to a first heat exchanger 2.

The solution passes across the primary side of the heat exchanger 2 and is fed to a heating arrangement 3. The solution is transported from the heating arrangement 3 in a delay conduit 15 of such length that the reside time permits sterilizing of the solution which has been heated by the heating arrangement 3.

The solution is fed from the conduit 15 to the heat exchanger 2 where the solution passes across the secondary side of the heat exchanger and heats the incoming solution on the primary side.

The solution is transported from the heat exchanger 2 to a second heat exchanger 6 and passes across its primary side. A heating medium is provided on the secondary side of the heat exchanger 6, which heating medium can be cold water if further cooling is required and which flows from an inlet 10 to an outlet 11. The solution flows from the heat exchanger 6 via a throttle arrangement 7 and a valve 13 to an outlet 9.

A shunt conduit 14 is connected between the inlet 5 downstream of the valve 12 and the outlet 9 upstream of the valve 13. The function of the shunt conduit is to allow recirculation of the solution in the system without any new solution being introduced via the inlet 5 or removed by the outlet 9. By shutting off the cooling means supply to the second heat exchanger 6, the solution in the closed circulating system can be heated to a high temperature, for example 120°C, for sterilizing the system.

In addition, a bleed valve 14 is arranged downstream of the throttle valve 7 and upstream of the outlet valve 13.

The connection unit 20 according to the invention is arranged in cooperation with the shunt conduit 14 and shown in Fig. 2. The connection unit has an inlet 21 for incoming solution from the throttle valve 7, an outlet 23 for solution which is to be recirculated in the shunt conduit 14 and an outlet 22 for exiting sterile solution.

In Fig. 3, the connection unit 20 according to the present invention is shown in a stand-by position. The connections of the various conduits according to Fig. 2 are shown in Fig. 3. Accordingly, there is an inlet 21 (positioned behind the unit 20 in Fig. 3) which is connected to the throttle valve 7 and the bleed valve 4. In addition, there is an outlet 23 to the shunt conduit 14. A piston 19 is shown in a closed position and closes the opening 22 which will be explained in greater detail below.

The inlet 21 opens into a cylindrical bore 25 via a tube 26 which is concentric with the bore 25 and which terminates with a penetration element in the form of a point 27. Solution from the throttle valve 7 can thus be fed via the inlet conduit 24 to the inlet 21 and subsequently to the tube 26 and, via the point 27, into the bore 25 and further via the outlet 23 to the shunt conduit 14.

In Fig. 3, the bore 25 is sealed at its upper end by the piston 19 which cooperates with an O-ring seal 28 arranged in the side of the bore.

The operation in the stand-by position as shown in Fig. 3 thus permits the sterilizing arrangement according to EP-A1-0 428 009 to be used with recirculation according to this document.

When the connection unit 20 is to be used for filling of a disposable set of tubes, a connector 30 as shown in Figs. 4 and 5 is used. Fig. 4 is a cross section through the connector. The connector consists of a cylinder 31 of such diameter that it fits in the bore 25 and seals against the O-ring 28. At the lower region of the cylinder 31 there is a reduced portion 32 on which a cover 33 is arranged. The cover 33 can be of rubber. In addition, the connector 30 has a semi-cylindrical-shaped engagement portion 34 of such dimension that the piston 19 fits therein. Finally, a connection portion 35 is provided to which a tube is connected. The tube leads to a container which is to be filled or some other suitable device such as a dialysis machine. In Fig. 5, the connector 30 is seen from above.

When the connection unit according to the invention is to be used to fill a container connected to the connector 30, this takes place in the following manner (see Figs. 6-8). Firstly, it is assured that the connecting unit is depressurized by means of opening the bleed valve 4. Thereafter, the piston 13 is displaced by means of a manoeuvre device 36 to the position shown in Fig. 6. By means of this displacement of the manoeuvre device 36, an opening 22 is revealed in the side of the connection unit which leads to a cavity 27. The bore 35 opens into this cavity. Accordingly, the opening to the bore 25 is exposed.

The connector 30 is introduced through the opening 22 so that the lower region 32 is located immediately above the bore 25 and can be downwardly displaced into the bore 25 so that the cylinder 31 cooperates with the O-ring 28. This position is shown in Fig. 7.

The correct introduction of the connector into the bore 25 is facilitated by means of the engagement portion 34 cooperating with the piston 19 and snap fastening therewith during the insertion of the connector 30 through the opening 22. Thereafter, the manoeuvre device is displaced downwardly to the position shown in Fig. 7.

As is evident from Fig. 7, the connector 30 is only partially introduced into the bore 25. The connector 30 is introduced into the bore 25 such a distance that the O-ring 28 cooperates with the cylindrical surface of the connector so that sealing of the bore 25 is achieved. At the same time, the connector 30 is so high up that the point 27 does not reach the cover 33 on the connector 30.

The sterilizing arrangement according to the Fig. 2 has a particular sterilizing position in which the solution is heated to a high temperature, for example 120°C. This is achieved by means of cold water no longer being supplied to the secondary side of the second heat exchanger 6 and that the heating arrangement 3 is operated so that the temperature in the recirculating system increases to 120°C. In this manner, the pressure in the entire circulation conduit rises to a pressure of about 2 atmospheres (absolute pressure, i.e. an overpressure of one atmosphere). This pressure arises automatically since the valves 12 and 13 are closed.

In the position shown in Fig. 7, the sterilizing arrangement is activated so that solution with a temperature of about 120°C circulates through the conduit 24, inlet 21, tube 26 and point 27 to the bore 25 and may flow around the cover 33 of the connector 30 and further via the outlet 23 to the shunt conduit 14 as described above. This position is maintained for as long as it requires for the bore 25 and the lower portion of the connector 30 to become sterilized.

When a sufficiently long period of time has elapsed for the sterilization to have been achieved, the drainage valve 4 is activated and the sterilizing arrangement is adjusted so that solution which is to be sterilized is introduced via the inlet 5 and is allowed to flow through the system. For this to occur, the shunt conduit 14 is closed by means of the valve 29 (see Fig. 3). The bleed valve 4 is open until normal operation is attained in the system.

When normal operation is attained, the manoeuvre device 36 is activated to press the connector 30 downwardly to its lower position as shown in Fig. 8 at the same time that the valve 4 is closed. In this position, the point 27 penetrates the cover 33 so that access is gained to the interior of the connector. At the same time, the outer peripheral portions of the cover 30 seal against the base of the bore so that the outlet 23 is closed off. In this manner, all solution which enters via the inlet 21 has to flow into the connector 30 and to a connected storage bag or dialysis machine or other medical equipment.

By means of this embodiment of the connecting unit, the outer portion of the connector 25 and the point 27 are sterilized before these two parts cooperate with each other. In this manner, the risk of bacteria entering the connector 30 when the cover or membrane 33 is penetrated is totally eliminated.

When filling of a storage bag is attained, the bag is sealed in a suitable manner, for example via heat welding in a known manner.

It is also possible to make the cover 33 of a rubber material provided with slots which seal in a sterile manner after removal of the point 27. Such a connector is previously known from EP-B1-0 116 986.

As has been previously mentioned, the sterilizing solution is heated to a high temperature, for example 121°C. The pressure in the bore 25 thus becomes about 2 atmospheres. In order to assure sterility, it is necessary that circulation continues for 20 minutes.

It may be desirable to reduce this time and this can be achieved by increasing the temperature to, for example, 130°C and a pressure of 2,7 atmospheres. In this manner, the time can be reduced to about two minutes. It must be ensured, however, that the hot sterilizing solution reaches all the regions which are to be sterilized.

As is apparent from Fig. 3, the cover 33 is provided with a depression in which the point 27 is positioned during the sterilizing cycle. The region which must be sterilized is this depression as well as the region of the cover which forms the seal against the base of the bore 25. In addition, the actual penetrating part 27 must be sterilized. An effective sterilizing at high temperature can be attained if the point 27 is shaped as a cone provided with a plurality of small holes. The sterilizing solution will thus spray the inside of the depression of the cover 33 which will thereby be intensely treated with sterilizing solution.

It is preferred that the cover 33 be made from a material which tolerates high temperatures up to at least about 150°C. The remaining part of the connector 33 can be more or less effectively insulated from the warm sterilizing solution, for example by means of the cover 33, which extends a certain amount upwardly along the cylindrical outer surface of the connector.

The connection unit according to the invention can of course be used independently of the sterilizing arrangement as is apparent from EP-A1-0 428 009. Thus an arrangement can be used as shown in Fig. 9. The sterile solution which is to be transferred to a container via the connector 30 is fed via a conduit 41 and a non-return valve 42. A pump 43 feeds the sterile solution in the conduit 41 to the inlet 21. When the connection unit is in the sterilizing position shown in Fig. 9, the solution which is introduced via the conduit 21 has to flow out through the outlet 23 to the shunt conduit 44. The shunt conduit extends via a heating arrangement 45 back to the inlet of the pump 43.

When the pump 43 is actuated, the solution circulates in a closed circuit via the inlet 21 through the bore 25 to the outlet 23 via the shunt conduit 44 and the heating arrangement 45 back to the pump 43. No further solution can be introduced via the inlet 41.

When the cover 33 of the connector 30 and the bore 25, as well as the penetrating element 27, are to be sterilized, the heating arrangement 45 is activated and heats the solution which circulates in the circuit to a temperature of about 120°C. The pressure in the circulating solution rises but because of the non-return valve 42 the solution does not boil. When the solution has circulated at 120°C for a sufficiently long time, for example about 20 minutes, the heating arrangement 45 is disconnected and the still circulating solution is allowed to cool. When a

sufficiently low temperature has been attained, which is measured by a temperature sensor 46, the manoeuvre device 36 is activated to press the connector 30 to the position shown in Fig. 8. The temperature at which this activation occurs is dependent on the material of the connector 30. If PVC-material is used, it is preferred that the temperature has decreased to at least 80°C. Measurements can alternatively be carried out using a pressure sensor 48, possibly in combination with the temperature sensor 46.

When the connector 30 is pushed down to its bottom position, the cover 33 seals the outlet 23 so that the circulation in the conduit 44 ceases. The pump 43 continues to operate and thereby draws solution from the conduit 41 via the non-return valve 42 and feeds the solution via the inlet 21 and the connector 30 to a storage bag or similar connected to the connector 30.

The sterilizing of the penetrating member 27 and the connector 30 can take place using the sterile solution which is introduced via the conduit 41 and which is heated with the heating arrangement 45.

Alternatively, pure water can be circulated in the circulation circuit 44. When the sterilizing is completed, a valve 47 is adjusted which is shown with dashed lines in Fig. 9 and the content in the pump 43, the inlet 21, the bore 25 and the outlet 23 can pass to an outlet at the same time as the sterile solution which is to be fed in passes through the conduit 41, the pump 43, the inlet 21 and to the bore 25 and further via the outlet 23. At the same time, the pressure drops to about atmospheric pressure. When a sufficiently long time has expired for all the water to have been replaced, the manoeuvre device 36 is activated so that filling is initiated.

An alternative embodiment of the bore 25 is shown in Fig. 10. Thus, the bore is provided with a lower expansion 51. In this manner, the sterilizing solution will circulate around the entire lower portion of the connector 30 so that it becomes sterilized. This embodiment is suitable if the connector 30 is made from a material which tolerates temperatures in the order of 120°C without deformation, such as polycarbonate.

Furthermore, the penetrating element 52 is provided with a conical region 53 which, when activation of the manoeuvre device and downward displacement of the connector 30 take place, cooperates with the cover or seal 33 of the connector at the same time that cooperation occurs with the base of the bore. In this manner, the region which has to be sterile to allow sterile transfer to be able to take place is further restricted.

In order to facilitate the recirculation, the conical region 52 is provided with a plurality of holes 54 so that the sterilizing solution can flow through the tip 55 of the penetrating element as well as through the opening 54. In this manner, a larger circulation flow is maintained during the sterilizing phase.

Two outlets 56 and 57 corresponding to the outlet 23 are shown in Fig. 10. These outlets can be tangentially arranged to ensure the best flow properties in the bore 25. It is also possible to use the conduit 56 as an inlet as well as the inlet 52 in order to further increase the flow. Further variations will be apparent to a skilled person. A further variant of the present invention is shown in Fig. 11 which can be used to connect a bag containing sterile solution to a machine in which the sterile solution is to be used, for example a dialysis machine or an infusion tube.

The sterile solution is in a storage bag or a device which is connected via a connector 30 on the left in Fig. 11. The connector 30 is connected to a connector 35 of a user who is to use the sterile solution. The two connectors 30 and 30' are each inserted in respective bores 25, 25' with respective points 27, 27'. The bores 25, 25' are connected to each other via a communication passage 61. During the sterilizing phase, a solution which can be water is circulated by the pump 8 to the tip 27', around the cover 33', into the bore 25' and via the communication passage 61 to the other bore 25, further around the cover 33, to the point 27 and via the heating arrangement 3 back to the pump 8. By activating the heating arrangement 3, the circulating solution is heated to about 121°C. In this manner, an inner pressure of about 2 atmospheres is reached. When the thus initiated sterilizing has gone on for about 20 minutes, a valve 62 is switched before the pump 8 to its second position so that the heating arrangement 3 is by-passed by the conduit 63. The circulation continues until the temperature which is sensed by a temperature sensor 64 has fallen to a safe temperature, for example about 60°C.

The second bore 25' is connected to a valve 66 and a flexible storage bag 67 via a conduit 65.

When the temperature has dropped to a suitable level, the manoeuvre device 36 is activated on the left-side connector 30 and presses the connector 30 down to its lower position. This causes the point 27 to penetrate the cover 33 and the cover 33 seals the passage 61 and the bore 25. A sterile connection between the connector 30 with the point 27 has been attained.

The sterile solution which is supplied via the connector 30 flows through the point 27, the conduit 63, the valve 62 and the pump 8 to the point 27'. The solution flows from the point 27' further to the bore 25'. Since the conduit 61 is closed at its left end by means of the cover 33, the solution cannot pass through the conduit 61. Instead the solution flows through the conduit 65 via the now open valve 66 to the storage bag 67.

When a sufficient quantity of sterile solution has flowed along this path and has displaced all solution which has been used for sterilizing, which occurs after say one minute, the manoeuvre device 36' is activated and connects the connector 30' with the point 27' which penetrates the cover 33' which simultaneously seals against the base of the bore 25'. In this manner, the conduit 25 is sealed off whereby the valve 66 can be closed. A sterile connection between the connector 30 and the connector 30' has now been attained.

In the embodiment of the connection unit which is shown in Figs. 3-9, the bore 25 is preferably arranged in a heat-insulating material such as polycarbonate. In this manner, the regions of the connector 30 above the cover 33 are prevented from being heated to a great degree during the sterilizing phase. This implies that cheap material for the connector 30, such as PVC, can be used without the risk of deformation during the sterilizing phase.

The sterile solution can be infusion solutions, dialysis solutions or other medical solutions such as physiological sodium chloride solution, e t c.

The sterile solution can also be water which is filled in bags via the connector. The bags contain a salt in powder form and are sterilized by suitable means so that the interior of the connector, the bags and their contents are sterile. When the bags are to be used, they are connected to the sterilizing arrangement 1 according to Fig. 2 and water is added to the bags. In this manner, the salt is dissolved and a medical solution is attained ready for use. The salt can contain several substances, such as a concentrate which is used in haemodialysis. The salt can also contain further substances such as medically active substances in connection with infusion.

Suitably, the sterile solution itself is also used for the sterilizing phase. That portion of the sterile solution which has been used for sterilizing can be disposed of and new sterile solution used for filling the connector.

As has been mentioned above, a particular solution such as physiological sodium chloride solution or water can be used for the heat-sterilizing phase of the connector's outer portion, whereafter the solution is disposed of and replaced by the sterile solution which is to be added to the connector, such as dialysis solution, peritoneal dialysis solution (containing i.e. glucose) infusion solution, e t c.

The invention is not restricted to the above-described embodiment but can be modified within the scope of the invention in a manner obvious for the skilled person. The various described components can be combined in other ways than those which have been shown in the drawings. The invention is limited only by the claims.

CLAIMS

1. Method for sterile transfer of a solution via a connector, **characterized**

in that the inlet opening of the connector is heat sterilized by flowing sterilizing solution around the inlet opening of the connector;

in that a penetrating element is sterilized by flowing a sterilizing solution around the penetrating element,

in that the sterilized inlet opening of the connector is penetrated by the sterilized penetrating element and said solution is transferred to the connector via the penetrating element.

2. Method according to claim 1, **characterized** in that the sterilizing is heat sterilization, which takes place at a high temperature above about 120°C and at a high pressure above about 2 atmospheres (absolute pressure).

3. Method according to claim 1, **characterized** in that the opening to the connector and the penetrating element are sterilized in the same cycle by the same sterilizing solution.

4. Method according to claim 3, **characterized** in that the sterilizing takes place in a bore in which the penetrating element is positioned and the connector is inserted, and in that the sterilizing solution circulates in a closed circuit comprising a heating arrangement.

5. Method according to claim 4, **characterized** in that the opening to the connector during penetration seals a region which has been sterilized during said circulation.

6. Connection unit for sterile transfer of a solution to a connector (30), comprising an inlet (21) for said solution, **characterized** by

a bore (25) to which the inlet (21) is connected, whereby the connector (30) is insertable into the bore (25);

a penetrating means (27) accommodated in a bore;

a recirculation arrangement (23, 14) for circulation of a heat sterilizing solution around the penetrating means (27) and a connector (30) inserted in the bore; and

a manoeuvre device (36, 19) for activating the penetrating means for penetrating the connector.

7. Connection unit according to claim 6, **characterized** by a sealing arrangement (33) for sealing of a region about the penetrating means (27) and a connector (30) which has been sterilized by the sterilizing solution.

8. Connection unit according to claim 6 or 7, **characterized** in that the sealing arrangement (33), during activation of the manoeuvre device (36, 13) and penetrating of the connector (30), also seals against the base of the bore (25) so that the recirculation arrangement is closed and a closed sterilized region is created.

9. Connection unit according to any one of claims 6-8, **characterized** in that the sterilizing solution is heated to a temperature above about 120°C and has a pressure of above about 2 atmospheres (absolute pressure).

10. Connection unit according to any one of claims 7-9, **characterized** in that the sealing arrangement (33) is in the form of a cover on the connector (30) through which the penetrating means (27) penetrates during activation of the manoeuvre device (36, 19).

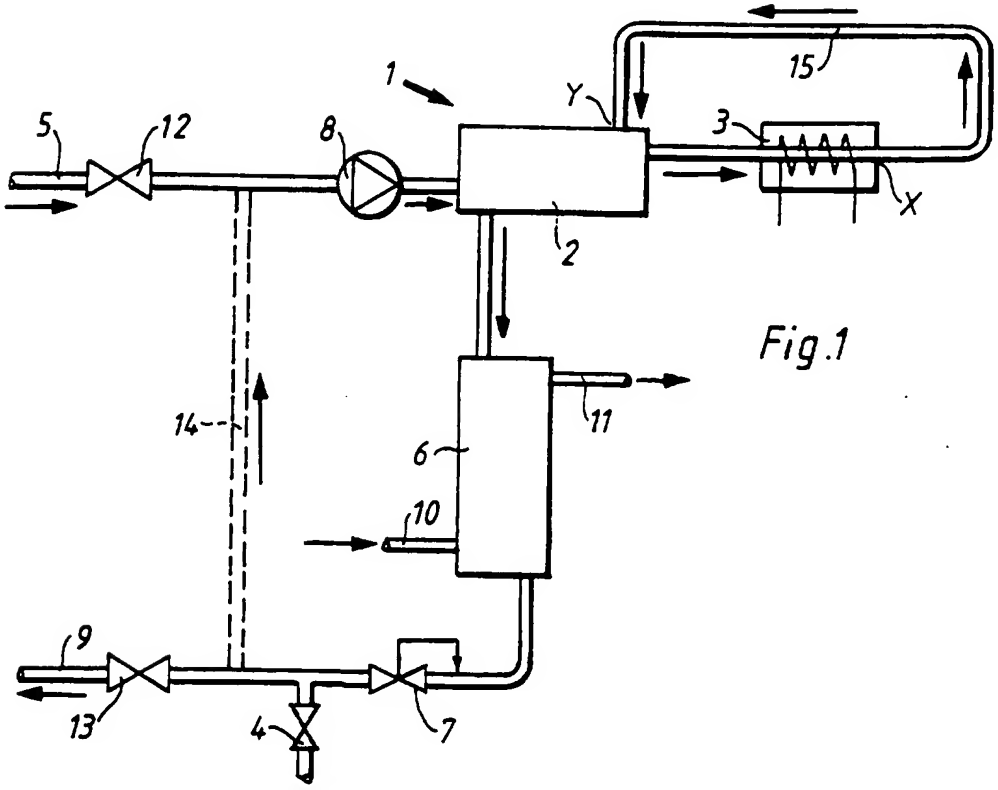
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Fig.1

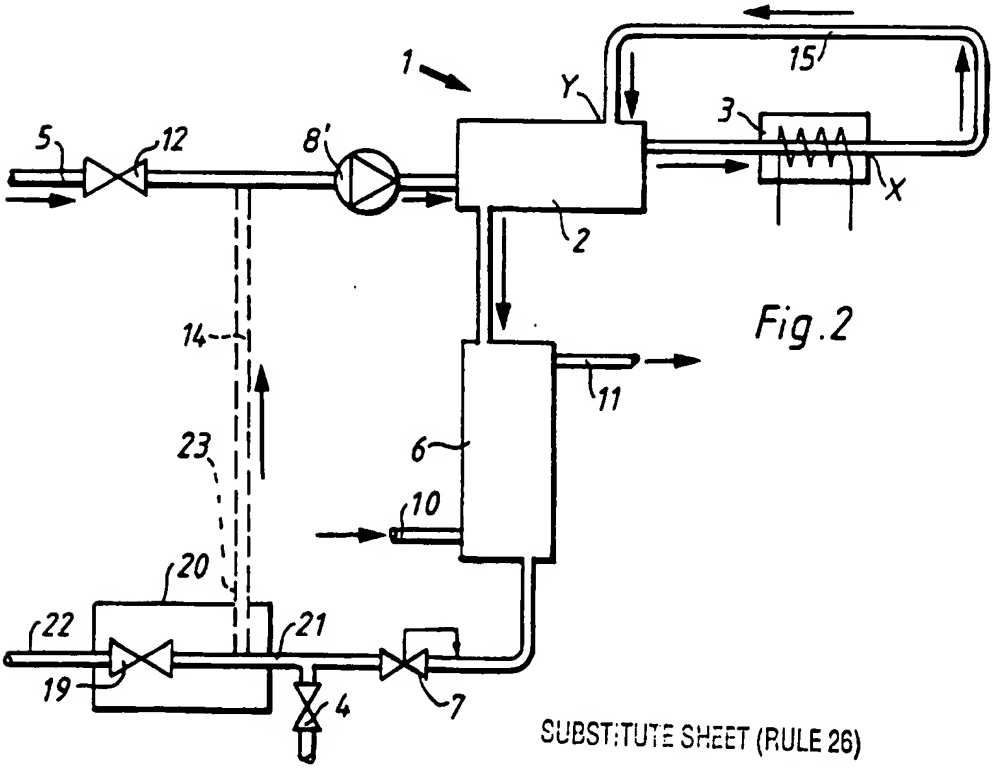
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Fig.2

Fig. 3

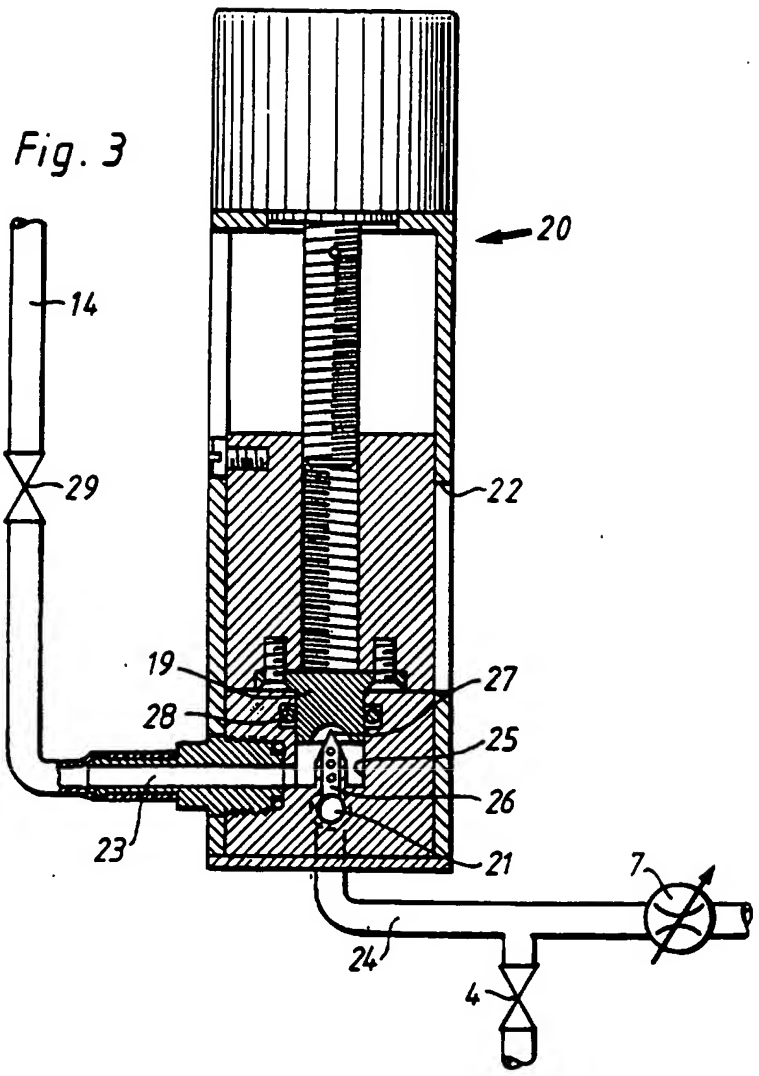

Fig. 4

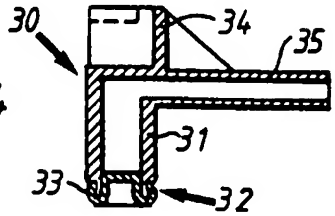

Fig. 5

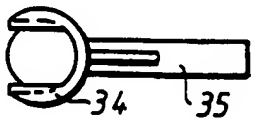

Fig.6

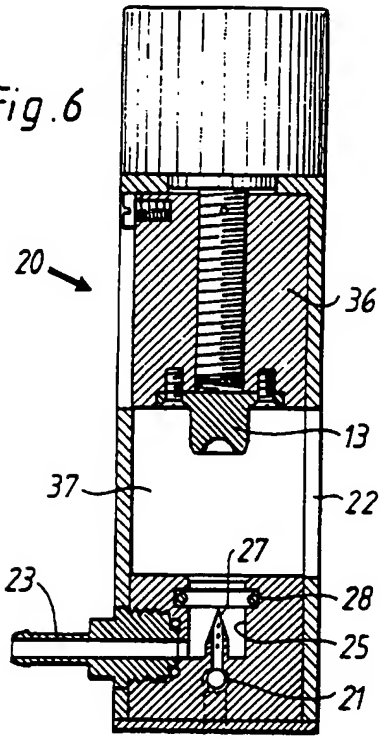

Fig.7

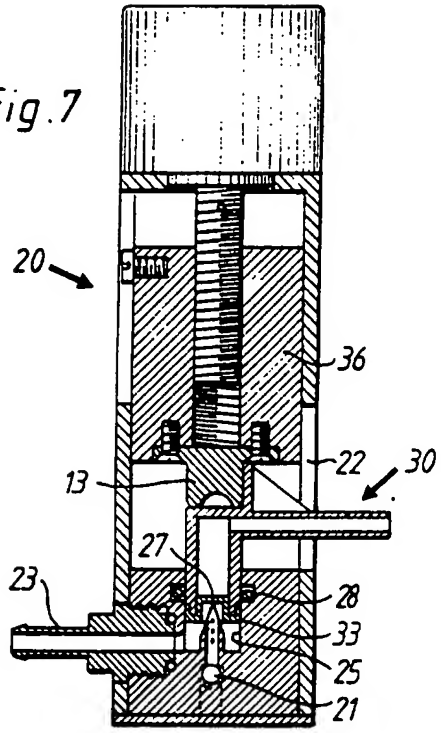

Fig.8

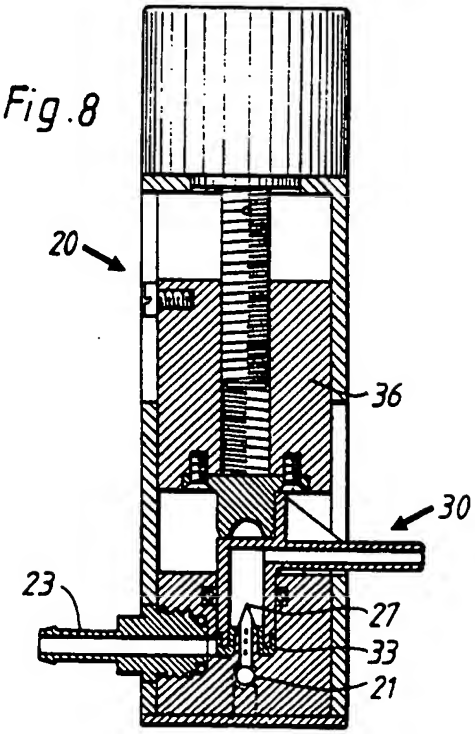

Fig. 9

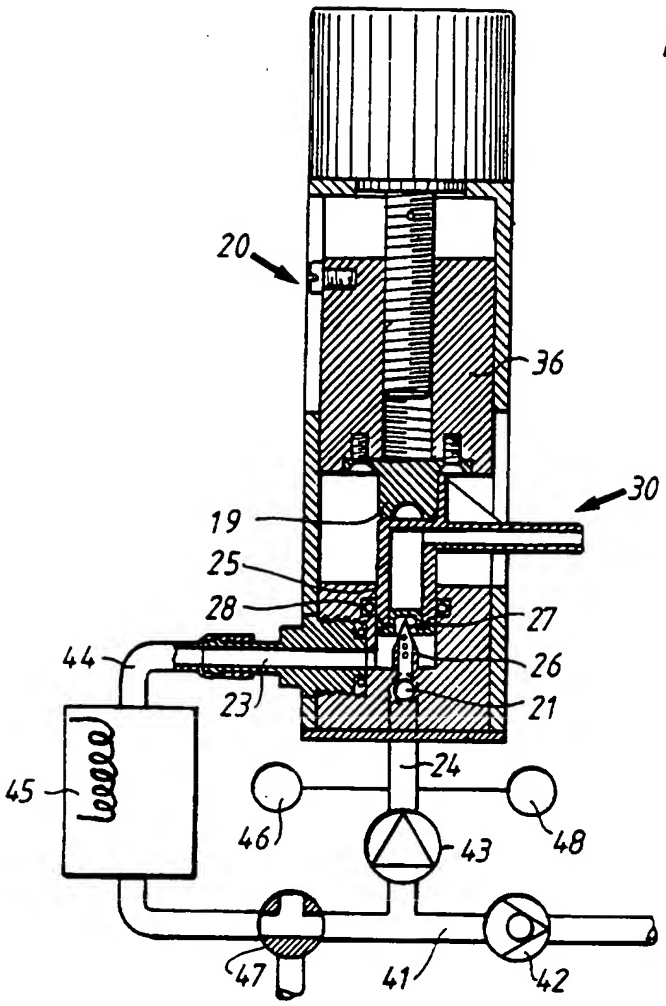
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Fig. 10

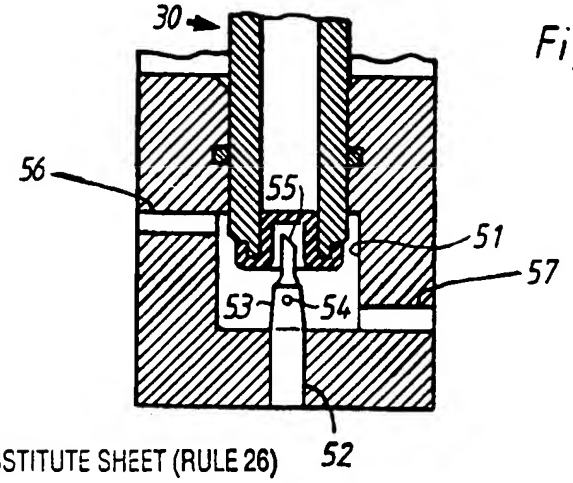
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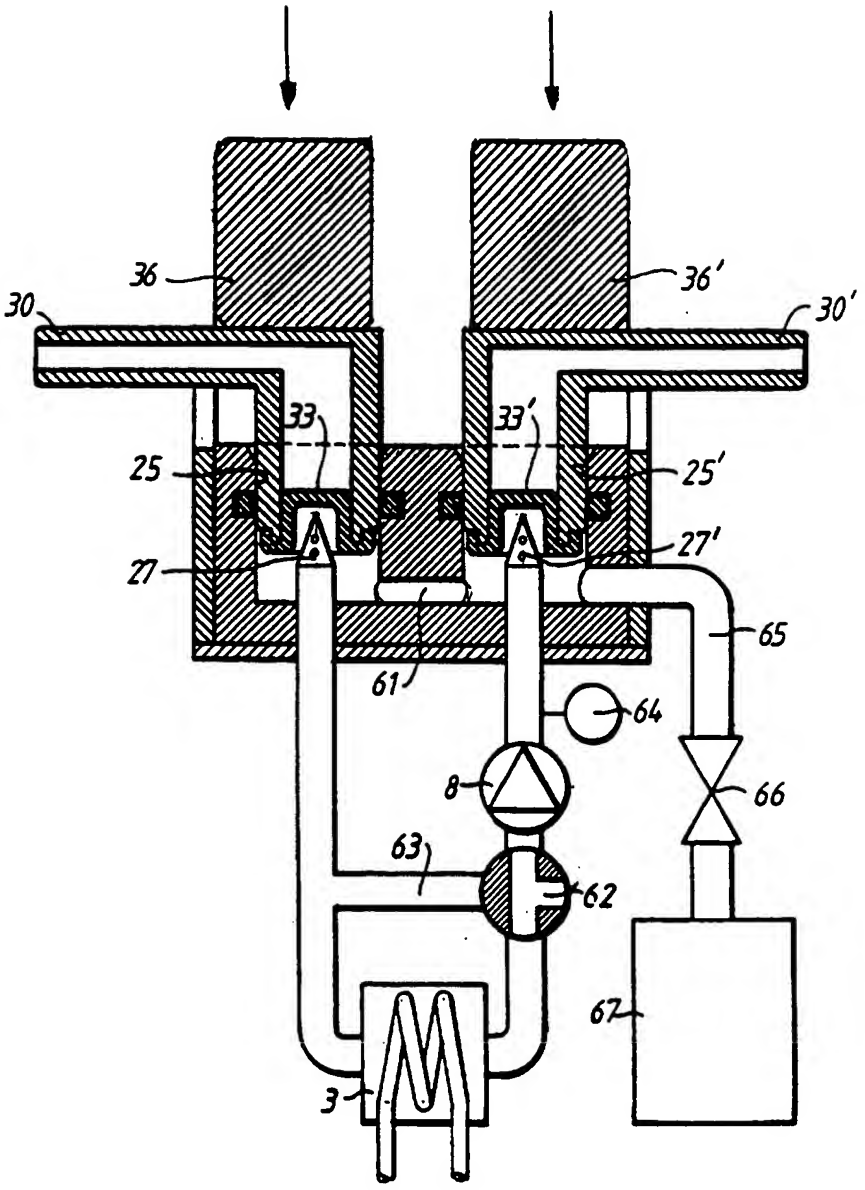
Fig. 11



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00795

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 39/18
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4673400 A (MARTIN), 16 June 1987 (16.06.87), see especially fig 2 and adherent text.	1,3
Y		2,9
	--	
Y	EP 0428009 A1 (LINDQVIST, STEN-BÖRJE ET AL), 22 May 1991 (22.05.91)	2,9
	--	
A	DE 2452858 A1 (TENCZAR, FRANCIS), 7 May 1975 (07.05.75), see especially fig 15-18 and adherent text.	1
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 December 1995	5.12.95
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Vingård Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00795

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0116986 A1 (STERITECH B.V.), 29 August 1984 (29.08.84) --	6,7
A	EP 0230864 A1 (BUONCRISTIANI, VINCENZO), 5 August 1987 (05.08.87) --	6,7
A	EP 0588375 A2 (MARRUCCHI, PIERO), 23 March 1994 (23.03.94) --	6,7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00795

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

One invention according to claims 1-5 referring to a process and one invention according to claims 6-10 referring to a product, where said product is in no way tied to be used in connection with said process.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

30/10/95

International application No.
PCT/SE 95/00795

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4673400	16/06/87	NONE	
EP-A1- 0428009	22/05/91	DE-D,T- 69013119	26/01/95
		ES-T- 2060894	01/12/94
		JP-A- 3268762	29/11/91
		SE-C- 500294	30/05/94
		SE-A- 8903855	17/05/91
DE-A1- 2452858	07/05/75	JP-C- 919207	22/08/78
		JP-A- 50079192	27/06/75
		JP-B- 52049280	15/12/77
		US-A- 4022205	10/05/77
		US-A- 4030494	21/06/77
EP-A1- 0116986	29/08/84	SE-T3- 0116986	
		AU-B,B- 568045	10/12/87
		AU-A- 2400484	09/08/84
		CA-A- 1240352	09/08/88
		JP-C- 1712769	27/11/92
		JP-B- 3076948	09/12/91
		JP-A- 59177056	06/10/84
		NL-A- 8300386	03/09/84
		US-A- 4610469	09/09/86
EP-A1- 0230864	05/08/87	NONE	
EP-A2- 0588375	23/03/94	NONE	